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ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,054	AMBROSE ET AL.	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-15 and 18-22* is/are pending in the application.

4a) Of the above claim(s) *2,3,13,14 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-12,15 and 18-21* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed November 12, 2008. Claims 1-21 were previously pending, with claims 2, 3, 13 and 14 withdrawn from consideration. Applicants cancelled claims 5, 6, 16 and 17, added a new claim 22 and amended claims 1, 4, 7-15 and 18-21. Claims 1-4, 7-15 and 18-22 are pending. Claims 1, 4, 7-12, 15 and 18-21 will be examined.

2. Newly submitted claim 22 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 22 is directed to a previously non-elected species, therefore it will not be considered.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Applicants' amendments overcame the following: all rejections and objections pertinent to cancelled claims 5, 6, 16 and 17; rejection of claims 18-21 under 35 U.S.C. 112, first paragraph, written description, since they no longer depend from claim16; objection to claims 18-21; rejection of claims 11,12 and 18-21 under 35 U.S.C. 112, first paragraph, enablement; rejection of claims 1, 6, 11, 15 and 17 under 35 U.S.C. 102(a) as being anticipated by Nishizato et al.; rejection of claims 4 and 12 under 35 U.S.C. 103(a over Nishizato et al. and Adeokun et al. All other previously presented rejections are maintained for reasons given in the "Response to Arguments" below.

4. This office action is made non-final because of new grounds for rejection.

Drawings

5. The drawings were received on November 12, 2008. These drawings are accepted. The replacement Fig. 3 obviates the previously presented objection.

Specification

6. The amendment filed on November 12, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants amended Table 1 to indicate that the *1a and *5 alleles contain Asn at position 130, and the *1b, *14 and *15 alleles contain Asp at position 130, with support indicated at page 20, lines 15 and 32 and page 21, line 13.

However, whereas these lines support the amendment for the *1a, *5 and *15 alleles, there is no support for the changes for the *1b and *14 alleles. Therefore these changes represent new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. This office action contains new grounds for rejection necessitated by amendment.

Response to Arguments

8. Applicant's arguments filed November 12, 2008 have been fully considered but they are not persuasive.

A) Regarding the rejections of claims 1, 4 and 7-10 under 35 U.S.C. 112, first paragraph, written description, Applicants argue that the law does not require that each species in the genus to be supported, and that it was well known in the art how to determine whether an allele was in linkage disequilibrium with another allele.

First, the test here is not whether one would know how to do it, but whether one would know that Applicant was in possession of the claimed genus. First, Applicants determined the presence of 13 polymorphisms in the OATP-C gene. Applicants' own analysis indicates that only the -118 A>C and the -1558 T>C polymorphisms were in linkage disequilibrium with the V174A

polymorphism. So even assuming that the other ten are as well, this is a very small number in a genus which has millions of members, since there are potentially hundreds of thousands of other polymorphisms on the same chromosome 12 in linkage disequilibrium with the V174A polymorphism, none of which were determined by Applicants, much less found to be in linkage disequilibrium with the OATP-C gene V174A polymorphism. Finally, none of these 12 additional polymorphisms were shown to be indicative of reduced transport ability for rosuvastatin by themselves.

Thus Applicants were not in possession of the invention as claimed.

B) Applicants' arguments regarding the rejection of claims 1 and 4-10 under 35 U.S.C. 112, first paragraph, scope of enablement are moot in view of restated rejection based on amended claims.

Claim Rejections - 35 USC § 112, first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

10. Claims 1, 4, 7-12, 15 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species

situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

This rejection addresses two issues: written description of the polymorphisms and the term "rosuvastatin".

I) Claim 1 is drawn to a method of diagnosis comprising:

(a) providing a biological sample from a human identified as being in need of treatment with rosuvastatin, wherein the sample comprises a nucleic acid encoding OATP-C;

(b) testing the nucleic acid for the presence, on at least one allele, of either (i) a codon encoding alanine at the position corresponding to position 174 of SEQ ID NO:1,

or (ii) an allele of a polymorphism in linkage disequilibrium with (i); and

(c) if either (i) or (ii) is found in at least one allele, diagnosing the human as likely to have reduced ability to transport rosuvastatin into liver cells.

Claim 11 is drawn to a method of diagnosis comprising:

(a) providing a biological sample from a human identified as being in need of treatment with rosuvastatin, wherein the sample comprises an OATP-C polypeptide;

(b) determining whether the amino acid of the OATP-C polypeptide corresponding to position 174 of SEQ ID NO:1 is a valine; and

(c) if the amino acid is not a valine, diagnosing the human as likely to have reduced ability to transport rosuvastatin into liver cells.

Therefore all of the claims 1, 4 and 7-10 encompass a genus of nucleic acids with polymorphisms which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named polymorphisms in SEQ ID NO: 1 (V174A) or SEQ ID NO: 2 (-26A>G, -118A>C, -309T>C, -878A>G, -903C>T, -1054G>T, -1215T>A, or -1558T>C) or SEQ ID NO: 3 (T2122G, C2158T, A2525C, or G2651A), representing 13 polymorphisms. Thus, applicant has express possession of only 13 particular polymorphisms in the OATP-C nucleic acid, in a genus which comprises hundreds of millions of different possibilities, since there are basically an infinite number of polymorphisms which are in linkage disequilibrium with a codon encoding alanine at position 174 of SEQ ID NO: 1. Further, the claims are drawn not to determining the polymorphism in a nucleic acid encoding SEQ ID NO: 1, but in any nucleic acid encoding an OATP-C gene, the structure, i.e., the nucleic acid sequence, of which has not been specified. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

In case of claim 11 and its dependent claims, Applicants showed that only Ala at position 174 of SEQ ID NO: 1 was correlated with reduced ability of OATP-C with SEQ ID NO: 1 to

transport rosuvastatin into the liver, not in any other OATP-C with potentially different amino acid sequence, like splice variants, for example, or other mutated OATP-C proteins.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the allele of a polymorphisms in linkage disequilibrium with a codon encoding alanine at position 174 of SEQ ID NO: 1 lack any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the 13 specific polymorphisms, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to "a polymorphisms in linkage disequilibrium with a codon encoding alanine at position 174 of SEQ ID NO: 1", for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as a polymorphisms in linkage disequilibrium with a codon encoding alanine at position 174 of SEQ ID NO: 1, without any definition of the particular polymorphisms claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise the 13 polymorphisms claimed. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

II) Claims 1, 4, 7-12, 15 and 18-21 are drawn to methods of diagnosing reduced ability to transport rosuvastatin into liver cells. However, Applicants did not provide the adequate written description of the term "rosuvastatin", i.e., there is no description of what structure corresponds to this term. Therefore, the claims lack adequate written description.

Enablement

11. Claims 1, 4, 7-12, 15 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The discussion below focuses on two aspects of the claims: the term "rosuvastatin" and the alleles of OATP-C polypeptide.

The nature of the invention and breadth of claims

Claims 1, 4 and 7-10 are broadly drawn to a method of diagnosis comprising:

(a) providing a biological sample from a human identified as being in need of treatment with rosuvastatin, wherein the sample comprises a nucleic acid encoding OATP-C;

(b) testing the nucleic acid for the presence, on at least one allele, of either (i) a codon encoding alanine at the position corresponding to position 174 of SEQ ID NO:1,

or (ii) an allele of a polymorphism in linkage disequilibrium with (i); and

(c) if either (i) or (ii) is found in at least one allele, diagnosing the human as likely to have reduced ability to transport the rosuvastatin into liver cells.

Claims 11, 12, 15 and 18-21 are broadly drawn to a method of diagnosis comprising:

(a) providing a biological sample from a human identified as being in need of treatment with rosuvastatin, wherein the sample comprises an OATP-C polypeptide;

(b) determining whether the amino acid of the OATP-C polypeptide corresponding to position 174 of SEQ ID NO:1 is a valine; and

(c) if the amino acid is not a valine, diagnosing the human as likely to have reduced ability to transport rosuvastatin into liver cells.

However, as will be further discussed, there is no support in the specification and prior art for the claimed methods in their full scope. The invention is a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Working Examples

The specification has not defined what the term "rosuvastatin" corresponds to, i.e., what is its chemical structure, therefore, it has not enabled a method of using it. Further, even if the structure was provided, the following has been established by Applicants.

The specification has a working example directed to a relationship between the V174A polymorphism of OATP-C protein with SEQ ID NO: 1 and the plasma levels of rosuvastatin, indicating that the presence of this polymorphism in heterozygous subjects correlates with the increased plasma levels of rosuvastatin, i.e., decreased uptake of the drug by hepatocytes. Applicants did not show that a polymorphism in any other OATP-C polypeptide corresponding to the V174 position is associated with decreased rosuvastatin uptake. Finally, Applicants did not show that polymorphisms in nucleic acids encoding either the polypeptide with SEQ ID NO: 1 or any other OATP-C polypeptide corresponding to the codon encoding Ala174 of SEQ ID NO: 1 or polymorphisms in linkage disequilibrium with such polymorphism are correlated with decreased rosuvastatin uptake by hepatocytes.

Guidance in the Specification.

The specification provides no evidence that the presence of a V174A polymorphism in OATP-C polypeptides other than the one with SEQ ID NO: 1 or the presence of alleles corresponding to the codon encoding Ala174 of SEQ ID NO: 1 in any nucleic acid encoding an OATP-C polypeptide results in a decreased uptake of rosuvastatin by the liver, or that any other

polymorphisms in linkage disequilibrium with such polymorphism have this property. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention.

The unpredictability of the art and the state of the prior art

The specification recites that the plasma levels of rosuvastatin was increased when the subjects were heterozygous for the V174A allele in OATP-C polypeptide with SEQ ID NO: 1. As stated by the inventors on page 25, lines 9-15:

"Evidence of an in vivo genotype-phenotype relationship has been determined between OATP-C variants and the pharmacokinetic profile of statins, a common class of drugs used in the treatment of hypercholesterolaemia/dyslipidaemia The observation of higher plasma concentrations of rosuvastatin in patients with the Ala174 OATP-C variant indicates that transport of rosuvastatin by the Ala174 variant is lower than that of the Val174 OATP-C variant. The Ala174 variant thus causes reduced uptake of statins in to the liver and consequent increased plasma levels. Plasma drug concentration is a factor in altering the benefit-risk ratio of statin therapy. OATP-C variants N130D and P155T do not appear to affect the pharmacokinetic disposition of rosuvastatin."

Aside from the V174A polymorphism, resulting from the 521 C>T base change (even though it is not clear what the numbering refers to, as no sequence has been provided for the nucleic acid encoding SEQ ID NO: 1) and the -118A>C polymorphism as detailed in SEQ ID NO: 2, there is no evidence that any other of the remaining 11 polymorphism discovered by Applicants are either in linkage disequilibrium with the 521 C>T polymorphism or have any effect on the rosuvastatin uptake.

As can be seen from the Reich et al. paper (Nature, vol. 411, pp. 199-204, 2001; cited in the IDS), SNPs in linkage disequilibrium with a given high-frequency SNP can be found as far away as 60 kb in Northern European population, for example (Abstract; Fig. 2). Further, the number of high-frequency SNPs and extent of LD for any given SNP are highly variable. As can be seen in Table 1 of Reich et al., for the four SNPs on chromosome 12, there are other connected SNPs extending as

far out as 160 kb. It has to be noted that for this study only subregions of 2 kb centered at distances 5, 10, 20, 40, 80 and 160 kb in one direction from each SNP were sequenced (page 199, third paragraph), i.e., the number of SNPs in LD with a given SNP would be much larger if the whole sequence of 160 kb were to be determined. Further, as stated by Reich et al., "blocks of LD are large" (page 200).

Therefore, the potential number of SNPs in linkage disequilibrium with the 521 C>T allele of the OATP-C protein is very large, and it cannot be predicted a priori from the chromosomal sequence. As stated by Reich et al. (page 200, last sentence, continued on page 201):

"Although the average extent is large, there is great variation in LD across the genomic regions (see also ref. 12), which is apparent in the different rates at which LD declines around the core SNP (Fig. 2). For example, [D'] > 0.5 for at least 155 kb around the *WASL* gene, but for less than 6 kb around PC/(Fig. 2). The variability across different genomic regions within the same population sample provides a context for explaining why past empirical studies, each based on one to three regions[3-5], have produced such different results. Large variations in LD are expected because of stochastic factors, such as different gene histories across loci[13]. Differences in recombination rates among regions can also affect the extent of LD. We observe a significant and important correlation (P 0.005) between LD and the estimated local recombination rate (Fig. 2, inset)."

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to apply these methods to detection of transport of any therapeutic agent into any cells. Large patient populations would need to be screened for the OATP-C protein with either the V174A polymorphism or any other alleles of the polymorphism in linkage disequilibrium with the V174A allele for rosuvastatin uptake to provide

statistically significant results in terms of the correlation between the presence of any of these polymorphisms and degree of rosuvastatin uptake. Further, ethnic differences in the action of the mutated proteins would need to be investigated. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where the effects of the OATP-C polymorphism on transport properties of rosuvastatin depend upon numerous known and unknown parameters such as the metabolism specific to the given drug and the drug's physicochemical properties, influence of age, health condition, ethnicity, etc., the factor of unpredictability weighs heavily in favor of undue experimentation. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of working examples and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 112, second paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 4, 7-12, 15 and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1, 4-12, 15 and 18-21 are indefinite over the recitation of "rosuvastatin". This term has not been defined in the specification in terms of its structure, therefore it is not clear what are the metes and bounds of the claims.

B) Claims 1, 4 and 7-10 are indefinite over the recitation of "a codon encoding alanine at a position corresponding to position 174 of SEQ ID NO: 1". It is not clear what this phrase means. First, "174" refers to an amino acid number in the amino acid sequence, and the claim is drawn to determining a nucleic acid sequence, so it is not clear what position within the nucleic acid sequence one needs to examine. Further, the claim is drawn to determining a position within an OATP-C gene "corresponding" to codon encoding amino acid at position 174 of SEQ ID NO: 1. Therefore, since no specific nucleic acid sequence is required for the OATP-C gene, it is not clear what a "corresponding" position means for such nucleic acids, since the claims encompass nucleic acids encoding OATP-C polypeptides differing in amino acid sequence from SEQ ID NO: 1.

C) Claims 11, 12, 15 and 18-21 are indefinite over the recitation of "amino acid corresponding to position 174 of SEQ ID NO: 1". It is not clear what this phrase means. The claim is drawn to determining a position within an OATP-C polypeptide "corresponding" to amino acid at position 174 of SEQ ID NO: 1. Therefore, since no specific sequence is required for the OATP-C polypeptide, it is not clear what a "corresponding" position means for such polypeptides, since the claims encompass OATP-C polypeptides differing in in amino acid sequence from SEQ ID NO: 1.

14. No references were found teaching or suggesting claims 1, 4-12, 15 and 18-21, but they are rejected for reasons given above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
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February 12, 2009